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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,016	09/10/2001	Janet A. Warrington	03848-00093	9580

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/950,016	WARRINGTON ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

1. It is noted that prior to the filing of the amendment of January 10, 2002, the claims had been renumbered in accordance with 37 CFR 1.126. The renumbering of claims (and correction of claim dependency in claims 33-34) had the same effect as the amendment of January 10, 2002; accordingly, the amendment was not entered. Claims 1-36 are now pending.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 7-14, and 18-25, drawn to methods of diagnosing cancer by detecting nucleic acids, classified in at least, for example, class 435, subclass 6.

II. Claims 3-6, drawn to methods of classify and differentiating cell types, classified in at least, for example, class 435, subclasses 6 and 325.

III. Claims 7-17 and 22-25, drawn to methods of diagnosing cancer by detecting proteins, classified in at least, for example, class 435, subclass 7.1.

IV. Claims 26-28 and 30-34, drawn to methods of assessing the efficacy of a compound *in vitro*, classified in at least, for example, class 435, subclasses 6 and 7.1.

V. Claim 29, drawn to methods of assessing the efficacy of a therapy *in vivo*, classified in at least, for example, class 424, subclass 9.2, and class 435, subclasses 6 and 7.1.

VI. Claims 35-36, drawn to kits comprising nucleic acid probes, classified in at least, for example, class 536, subclass 24.31.

3. It is first noted that applicant has presented several claims that encompass methods of detecting nucleic acids as well as methods of detecting proteins. Such claims are improper as nucleic acids and polypeptides are structurally and functionally distinct molecules. Nucleic acids are composed of nucleotides and function in, e.g., methods of hybridization, while proteins are composed of amino acids and function in, e.g., enzymatic methods or binding assays. Further, the method steps and reagents required to detect nucleic acids are separate and distinct from those required to detect proteins. Regarding claims 7-14 and 22-25, the claims have been included in multiple groups (Group I and Group III), and if either of these groups is elected, will be examined only to the extent that they are drawn to the elected invention. Groups IV and V include only claims encompassing detection of both nucleic acids and proteins. As nucleic acids and proteins are improperly joined in the claims of Groups IV and V, **upon election of either of these groups, applicants must further elect either nucleic acids or polypeptides**. See also *Ex parte Markush*, 1925 C.D. 126 and *In re Weber* 198 USPQ 328.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions VI and I, VI and II, VI and III, VI and IV and VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention VI can be used in a materially different process, such as methods of genomic mapping, methods of cloning and expressing novel homologous genes, etc.

Inventions I, II, III, IV and V are patentably distinct methods having different objectives and/or requiring the use of different reagents in different process steps. Invention I requires steps of contacting cells with arrays of nucleic acid probes to determine nucleic acid levels and diagnose cancer. Invention II requires steps of classifying and "ordering" cells to achieve the objective of differentiating cell populations. Invention III requires steps of contacting cells with antibodies to determine protein levels and diagnose cancer. Invention IV requires steps of exposing samples to test compounds to achieve the objective of assessing efficacy. Invention V requires steps of providing therapeutic agents to a subject to achieve the objective of assessing the efficacy of therapy in said subject. Accordingly, Inventions I-V are patentably distinct from one another.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-VI require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
March 21, 2003